Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Ronald A. Guzman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 1867	DATE	11/2/2004
CASE TITLE	ABBOTT LABORATORIES, et al vs. BAXTER PHARMACEUTICAL PRODUCTS, INC		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] ENTER MEMORANDUM OPINION AND ORDER: Plaintiffs' motion limine to bar the introduction by defendants of certain statements made by Abbott to the Food and Drug Administration and the U.S. Pharmocepia [162-1] is denied.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.			
	Notices mailed by judge's staff.		NOV 03 2004 date docketed	
	Notified counsel by telephone.			
✓	Docketing to mail notices.		docketing deputy initials	203
	Mail AO 450 form.			
	Copy to judge/magistrate judge.		date mailed notice	
CG	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, an Illinois Corporation, and CENTRAL GLASS COMPANY LTD., a Japanese Corporation,	)	
Plaintiffs,	)	
v.	)	**Judge Ronald A. Guzmán**
BAXTER PHARMACEUTICAL PRODUCTS, INC., a Delaware Corporation, and BAXTER HEALTHCARE CORP., a Delaware Corporation,	)	**01 C 1867**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Abbott Laboratories and Central Glass Company Ltd. have filed a motion in limine to bar the introduction by Defendants Baxter Pharmaceutical Products, Inc. and Baxter Healthcare Corp. of statements made by Abbott to the Food and Drug Administration ("FDA") and the United States Pharmocepia ("USP") indicating that Baxter's proposed generic sevoflurane does not have a water content effective to prevent degradation of the sevoflurane by Lewis acids. For the reasons provided in this Memorandum Opinion and Order, the Court deems admissible statements made by Abbott in its letters to the FDA and USP regarding whether Baxter's proposed product as described in its ANDA contains an effective amount of Lewis acid inhibitor as well as statements indicating that a water content of 300 ppm is required to prevent effectively degradation regardless of the container.

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FACTS

Baxter first developed sevoflurane, a fluorine-based inhalation anesthetic for patients undergoing surgery, in the mid-1960's. Abbott Laboratories is the sole seller of sevoflurane in the United States until December 2005 due to a complicated licensing agreement. Abbott has several patents for inhibiting degradation of liquid sevoflurane by Lewis acids, which can result in harmful by-products. Abbott's U.S. Patent No. 5,990,176 ("the '176 patent"), issued on November 23, 1999, teaches that to stop degradation, an effective stabilizing amount of Lewis acid inhibitor (one of which is water) must be added to the sevoflurane.

This complaint arises out of an Abbreviated New Drug Application ("ANDA") filed by Baxter in June 2000 seeking approval to sell generic sevoflurane with a water level of not more than 130 ppm in aluminum containers lined with an epoxyphenolic liner. Baxter made a paragraph IV certification that its generic sevoflurane does not infringe the '176 patent. Abbott filed suit alleging infringement of the '176 patent under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). The Court granted Baxter's motion for summary judgment, limiting the meaning of "effective amount" to amounts greater than 130 ppm due to a disclosure made by Abbott during patent prosecution that sevoflurane was sold with a water level of 131 ppm more than one year prior to the filing of its patent application. *Abbott Labs. v. Baxter Pharm. Prods.*, No. 01 C 1867, 2002 WL 449007, at *6 (N.D. Ill. Mar. 22, 2002), *vacated and remanded by* 334 F.3d 1274 (Fed. Cir. 2003). The Federal Circuit vacated and remanded the case, disagreeing with the Court's decision restricting effective amounts to those above 130 ppm and interpreting the scope of claims 1 and 6 of the '176 patent "to a single Lewis acid inhibitor selected from the recited Markush group, and present in an amount effective to prevent degradation of sevoflurane by Lewis acids." *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d at 1281.

In 2001, Abbott filed submissions with both the FDA and the USP in an apparent attempt to prevent approval of Baxter's ANDA for generic sevoflurane. Both correspondences indicated that Baxter's proposed product, generic sevoflurane with a water content of 130 ppm in a lined aluminum container, did not have an effective amount of Lewis acid inhibitor (water) to prevent degradation. Abbott further stated that 300 ppm of water would be required to "maximize the safety profile of the product." Abbott seeks to bar admission of these statements.

DISCUSSION

This case hinges on whether the statements made by Abbott to the FDA and the USP are going to be considered for the purposes of claim construction or for the purposes of determining infringement. If these statements are to be introduced into evidence for the purposes of claim construction, as Abbott claims, then certainly they are not admissible, as the court will accept the findings of the Federal Circuit as to the construction of the claims of the '176 patent. *See generally Abbott*, 334 F.3d 1274 (construing the claims of the '176 patent). The Supreme Court has stressed the need for this "intrajurisdictional certainty" by making claim construction a legal issue that in turn imposes the application of *stare decisis* on patent interpretation, making the Federal Circuit's claim construction of the '176 patent legal precedent in this case. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390-91 (1996). Any statements made that alter or further define the Federal Circuit's determinations on claim interpretation will not be admissible. However, determination of patent infringement, including whether an imprecise claim limitation is literally met, is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1280 (Fed. Cir. 1988). The Court must look to the statements themselves to determine whether they qualify as construction

of the claims of the '176 patent or whether they qualify as evidence of Baxter's alleged infringement of the '176 patent.

The Federal Circuit has provided the clearest guidance on the interpretation of the claims of the '176 patent – "[t]o prove literal infringement of these claims on remand, Abbott must show a species selected from the members of the recited Markush group is present in Baxter's sevoflurane composition in an amount effective to function as a Lewis acid inhibitor." *Abbott,* 334 F.3d at 1283. Moreover, the court specifically noted that the container used could influence what amount would be effective by stating "the specification clarifies that, at least with respect to glass containers, the amount of Lewis acid inhibitor varies depending upon the type of glass and other characteristics and conditions of the container." *Id.* Any statements made by Abbott that contradict the holding of the Federal Circuit on construction of the claims are therefore inadmissible.

On the other hand, infringement is determined by comparing the accused product with the claims of the patent, not with the preferred embodiment in the specification or a commercial embodiment. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). Therefore, any statements made by Abbott that relate to the effectiveness of Baxter's Lewis acid inhibitor (130 ppm water) in its proposed aluminum container, both specified in its ANDA, are relevant. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (noting that "an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.")

In Abbott's June 18, 2001 letter to the FDA and 2001 submission to the USP, it attempted to convince both organizations that Baxter's proposed generic sevoflurane product, with a water level of 130 ppm or less in a lined aluminum container, would be susceptible to

degradation by Lewis acids. Abbott noted that reducing the water level to such low levels may "significantly and negatively alter the safety profile of sevoflurane." Further, the letter stated, "Baxter's sevoflurane formulation raises serious safety and stability issues because the amount of Lewis acid inhibitor in Baxter's product may not prevent degradation when exposed to Lewis acids." Abbott also stated that alternative non-glass containers (such as Baxter's proposed lined aluminum container) were not adequate to protect the sevoflurane from Lewis acids and that 300 ppm of water would be necessary to "maximize the safety profile of the product." Abbott concluded that reduction of the water level "to minimal levels may dramatically and negatively alter the safety profile of sevoflurane, regardless of the container system."

Abbott's statements do not interpret the claims of the '176 patent but are opinions as to what constitutes an effective amount of Lewis acid inhibitor in Baxter's proposed ANDA, which is an issue for the trier of fact in this case. Abbott's specific statement regarding Baxter's product and the effectiveness of a Lewis acid inhibitor at 130 ppm in Baxter's proposed container and Abbott's general statement regarding the effectiveness of a Lewis acid inhibitor at 300 ppm in any container, are relevant and admissible. The Federal Circuit noted in interpreting the claims of the '176 patent that the container used would make a difference, and the patent itself does not address the specific container utilized by Baxter. *Id.* at 1283. Infringement in this case, a factual determination, is dependent on whether a water level of 130 ppm is effective to prevent degradation of sevoflurane by Lewis acids in a lined aluminum container. Statements made by Abbott in these letters (*e.g.*, indicating that the water level in Baxter's product "may significantly and negatively alter the safety profile of sevoflurane," "Baxter's sevoflurane formulation raises serious safety and stability issues because the amount of Lewis acid inhibitor in Baxter's product may not prevent degradation when exposed to Lewis acids") are relevant to

the factual determination of whether Baxter's product has an effective amount of water. The admissibility of these statements does not in any way suggest the weight they will be given, in light of the context of the statements that were made when Abbott was lobbying the FDA to reject Baxter's ANDA, the fact that both agencies rejected Abbott's position, and the fact that Abbott did not have an actual physical sample of Baxter's sevoflurane and packaging on which to base these statements.

Abbott cites several cases in support of its position that the statements made to the FDA and the USP should not be admissible. In *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, Zenith was applying for an ANDA for cefadroxil DC, and Bristol made statements to the FDA that Zenith's formulation did not conform to the monohydrate monograph and was in fact a hemihydrate. No. CIV. A. 91-3423, 1991 WL 267892, at *2 (D.N.J. Dec. 12, 1991), *rev'd on other grounds*, 19 F.3d 1418 (Fed. Cir. 1994). Nonconformance would have required Zenith to endure the full FDA approval process but would indicate potential non-infringement. *Id.* The court ruled that Bristol was not judicially estopped from claiming infringement because its statements to the FDA, even though the word "infringe" was specifically used, were not inconsistent with its theory of infringement under a theory of equivalence because the pre-ingested product differed from the post-ingested product (*in vivo* infringement). *Id.* at *12.

Zenith may be distinguished from the case at bar because Baxter is not seeking to judicially estop Abbott from claiming infringement. "The doctrine of judicial estoppel is that where a party successfully urges a particular position in a legal proceeding, it is estopped from taking a contrary position in a subsequent proceeding where its interests have changed." *Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1565 (Fed. Cir. 1996). In this case, the letters to the FDA were neither made in the context of a legal proceeding, nor successful, as Baxter's ANDA was

approved in spite of Abbott's efforts.

Further, Abbott cites a Seventh Circuit decision which espouses the doctrine allowing a party to take different positions in a suit, as long as one of the positions is not inconsistent with a prior judgment. *Astor Chauffered Limousine Co. v. Runnfeldt Inv. Corp.*, 910 F.2d 1540, 1548 (7th Cir. 1990). Again, Abbott's reliance is misplaced - the statements made to the FDA and the USP are not inconsistent statements in a legal proceeding. Abbott is basically arguing that a statement made outside of court against a party's own interest can never be admissible, which is a position the Court will not adopt.

Next, Abbott cites *Arthrocare Corp. v. Smith & Nephew, Inc.*, a case in which Smith argued that Arthrocare's 510(k) submissions to the FDA should have been admitted as relevant evidence in determining patent validity. 310 F. Supp. 2d 638, 667 (D. Del. 2004). The court found that the 510(k) submissions were not relevant to the validity analysis because anticipation is determined by comparing the claims in the patent to the prior art (not the 510(k) submissions to the prior art) and enablement is evaluated based on the specification (not based on the 510(k) submission). *Id.* The issues in this motion in limine relate to infringement and not to validity. Abbott's statements made to the regulatory agencies are not being used to re-construe the claims of the '176 patent or alter the Federal Circuit's construction of the claims - the claims cover an amount of Lewis acid inhibitor effective to prevent degradation, and this determination is not affected in any way by Abbott's statements. *See Abbott,* 334 F.3d at 1283. The admissible statements are those that relate to the factual issue of the effectiveness of the product described in Baxter's ANDA.

Finally, Abbott attempts to support its argument by citing *Clintec Nutrition Co. v. Baxa Corp.*, where the District Court found that an alleged infringer's 510(k) submission was not

admissible in an infringement inquiry. 988 F. Supp. 1109, 1116 n.18 (N.D. Ill. 1997). Baxa Corp. filed the 510(k) submission, which stated that its compounder was substantially equivalent to Clintec's patented compounder. *Id.* The court did not allow admission of the 510(k) submission because it compared the accused product to the patentee's commercial embodiment rather than the claims of the patent. *Id.* The case at bar can be distinguished because the statements at issue here were made by the patentee and relate directly to the infringement inquiry, which is whether Baxter's proposed product has an effective amount of Lewis acid inhibitor. Moreover, the Court will not be comparing Baxter's proposed product to Abbott's commercial embodiment. The only comparison will be the potentially infringing product to the already construed claims of the '176 patent.

Abbott also argues that use of statements made four years after the patent had been submitted is "akin to introducing evidence of a tort defendant's remedial efforts to determine negligence," which are prohibited under Federal Rule of Evidence ("Rule") 407. (Pls.' Mot. Limine (II) at 4.) The policy behind Rule 407 is that it "encourages desirable repairs by assuring defendants that precautions taken after a mishap are not to be admissible against them as evidence of their past negligence." *Rimkus v. Northwest Colo. Ski Corp.*, 706 F.2d 1060, 1064 (10th Cir. 1983). The Court fails to see the parallel between precautionary efforts taken after an accident and a letter written to an administrative agency to prevent a competitor from getting approval of a generic drug. The policy behind the rule is also not supported by Abbott's position - this is a patent case, not a products liability action where Abbott's actions are related to an injury claim. Extension of Rule 407 beyond its scope, especially in the completely unrelated area of patent law, is unwarranted.

In summary, the statements in the letters that indicate 300 ppm of water is required

regardless of the container and the statements made by Abbott which relate to the effectiveness of 130 ppm of water in Baxter's lined aluminum container are admissible, as they are relevant to the factual issue of infringement.

CONCLUSION

After careful consideration, the Court deems admissible statements made by Abbott in its letters to the FDA and USP regarding whether Baxter's proposed product as described in its ANDA contains an effective amount of Lewis acid inhibitor and statements made in those letters indicating that a water content of 300 ppm is required to effectively prevent degradation regardless of the container.

SO ORDERED **ENTERED:** 11/2/04

HON. RONALD A. GUZMAN
United States District Judge